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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,569	08/25/2000	ANDERS HJELHOLT PEDERSEN	02-107600US	5794

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EXAMINER

HOLBROOK, PAMELA G

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 03/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/648,569

Applicant(s)

PEDERSEN ET AL.

Examiner

Pamela G Holbrook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-53, drawn to polypeptide interferon conjugates classified in class 530, subclass 350.
 - II. Claims 52-56 and 66-72, drawn to DNA, vector, host cell and method to produce protein recombinantly classified in class 536, subclass 23.5, class 435, subclass 320.1, class 435, subclass 325 and class 435, subclass 69.1 respectively.
 - III. Claims 60-62, drawn to pharmaceutical compositions, classified in class 514, subclass 2.
 - IV. Claims 57-58, drawn to a method to reduce immunogenicity, classified in class 435, subclass 69.51.
 - V. Claims 59, drawn to a method to prepare an interferon conjugate, classified in class 435, subclass 70.5.
 - VI. Claims 63-65, drawn to methods to treat a mammal, classified in class 435, subclass 69.51.

2. The inventions are distinct, each from the other because of the following reasons:
Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to completely different products having completely different structures and biological functions which are not interchangeable and which require non-cohesive searches and considerations.
3. Inventions IV – VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different disclosed effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to completely different method steps, using different compositions and having completely different outcomes. The invention of group IV drawn to a method to reduce immunogenicity requires an assay for immunogenicity and does not require the steps to produce a conjugate of the invention of group V nor does it require the therapeutic outcome of the invention of group VI. The invention of group V drawn to a method to prepare a conjugate requires steps to produce the conjugate but does not require the assay for immunogenicity of the invention of group IV nor does it require the therapeutic outcome of the invention of group VI. The invention of group VI drawn to a method to treat a mammal requires a therapeutic outcome but does not require the assay

for immunogenicity of the invention of group IV nor does it require the steps to produce a conjugate of the invention of group V.

4. Inventions I and IV or VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: 1) the process for using the product as claimed can be practiced with another materially different product or 2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide conjugate can be used in a materially different process, such as making an antibody.
5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
6. Because these inventions are distinct for the reasons given above and the literature search required for any single group is not required for any other group, restriction for examination purposes as indicated is proper.
7. Restriction to one of the following inventions is also required under 35 U.S.C. 121:

Inventions 1–38 as they pertain to SEQ ID NO: 1 - SEQ ID NO: 38 respectively.

8. The inventions are distinct, each from the other because of the following reasons:
Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOS: 1-38 is a unique sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches. Each of the sequences represents a novel structure with a potentially different pharmaceutical property.
9. Because these inventions are distinct for the reasons given above and the search required for any single group is not required for any other group, restriction for examination purposes as indicated is proper.
10. **In order to be fully responsive, Applicant must select one from Groups I-VI, and one from 1-38. Applicant is advised that neither I-VI nor 1-38 are species election requirements; rather, each of I-VI and 1-38 is a restriction requirement.**
11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least

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one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pamela Holbrook whose telephone number is (703) 306-3221, Mon.- Fri. 8:15 am to 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623

The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [gary.kunz@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March 18, 2002

Gary L. Kunz
GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600